

REMARKS

The Final Office Action sent January 3, 2008 has been received and reviewed. All claims currently under consideration stand objected to or rejected. Applicants note with appreciation the withdrawal of the previous objections and rejections.

All amendments are made without prejudice or disclaimer. Support for the amendments can be found throughout the Specification, for example, in paragraphs [0063], [0064], and the claims as previously presented. Accordingly, no new matter has been added. Reconsideration is respectfully requested.

Claim Objections

Claims 1, 27, 46, and 47 stand objected to due to a typographical error. The claims have been appropriately amended.

35 U.S.C. § 112

Claims 1-4, 8-10, 27-30, and 46-47 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter not described in the specification in such as way as to reasonably convey that the inventors had possession of the claimed methods. Office Action of Jan. 3, 2008, page3. Applicants respectfully traverse as follows.

Applicants note, and acknowledge the Examiner's comments, that a sequence can meet the written description requirement under *Enzo Biochem, Inc. v. Gen-Probe Inc.* through the showing "relevant identifying characteristics *i.e.* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. 296 F.3d 1316, 1324 (Fed. Cir. 2002) (emphasis added). Applicants respectfully note that added emphasis on "or" which applicants submit clearly indicates that one does not have to meet each and every one of the test outlined by the *Enzo* court, but that any one of them can be met to satisfy the written description requirement.

Applicants further note that the genus of "variants" can also be provided with adequate written description "through sufficient description of a representative number of species by actual

reduction to practice.” M.P.E.P. § 2163(II)(A)(3)(a)(ii) Further “what constitutes a ‘representative number’ is an inverse function of the skill and knowledge in the art.” *Id.* Applicants respectfully submit that the skill and knowledge concerning nucleotides sequences in the biotechnological arts is very high.

As currently amended, claims 1, 27, 46, and 47 recite, *inter alia*, providing a yeast cell with an isolated or recombinant nucleic acid encoding *Plasmodium f.* ectodomain or a fragment thereof. The claims further define the encoding nucleic acid and/or fragments thereof in accordance with the subject matter described in the Specification (*e.g.*, “wherein the encoding nucleic acid comprises the nucleotide sequence of FIG. 1” and “wherein the fragment thereof comprises an amino acid sequence selected from the group consisting of 25-442, 97-442, and 97-545 of SEQ ID NO: 6”).

In the pending Office Action, the Examiner first alleges that a reasonable interpretation of the claim language “the amino acid sequence corresponding to amino acid residues” reads on sequences that could be homologous or analogous to those of SEQ ID NO:6, and are therefore not adequately described in the Specification. *See*, Office Action of Jan. 3, 2008, page 4. The Examiner further alleges that the claimed methods are “directed to a genus of any nucleic acid molecule encoding any portion of any Plasmodium AMA-1 ectodomain having protective immunogenic functionality.” *Id.* at 5. While the applicants do not necessarily agree that the Specification does not adequately describe such claims, in order to expedite prosecution, each of claims 1, 27, 46, and 47 has been amended substituting “functional part” with “fragment,” or “fragment thereof,” in addition to deleting “corresponding to.” Additionally, the amended claims further clarify “fragment,” or “fragment thereof” as comprising an amino acid sequence selected from the group consisting of 25-442, 97-442, and 97-545 of SEQ ID NO: 6. Applicants submit that the claimed fragments are more than adequately described in the Specification. Indeed, the Examiner acknowledges description and guidance with regard to the claimed “fragments” or “fragments thereof.” *Id.*

The Examiner further alleges that the term “comprises a nucleotide sequence of FIG. 1” reads on any consecutive sequences of at least two nucleotides. *Id.* at 4. While the applicants do not necessarily agree that the Specification does not adequately describe such element, in order to expedite prosecution, the amended claims now recite, *inter alia*, “wherein the nucleic acid

comprises the nucleotide sequence of FIG. 1.” Thus, the claims, as presently amended, are directed to subject matter described in the Specification.

The Examiner also alleges that the phrase “wherein at least one glycosylation site is removed from said *Plasmodium falciparum* AMA-1 ectodomain” is read as only limiting the AMA ectodomain, but not the functional part thereof. *Id.* Although, the applicants do not necessarily agree with the Examiner, in order to expedite prosecution, the amended claims now recite, *inter alia*, wherein at least one glycosylation site is removed from said *Plasmodium falciparum* AMA-1 ectodomain or said fragment thereof. Thus, the claims, as presently amended, are directed to subject matter described in the Specification.

The Examiner additionally asserts that the language of claim 8, allegedly reads “broadly on any tri-nucleotide sequence encoding a single amino acid present in said Vietnam-Oak Knoll strain.” *Id.* Applicants note that claim 8 depends from claim 1, thereby including all of the elements of claim 1. As such, applicants respectfully submit that the Examiner’s remarks with regard to claim 8 are now moot in light of the amended claims and remarks presented herein.

Applicants submit the Specification provides more than adequate written description of the presently amended claims. In light of the claim amendments and remarks presented herein, applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph rejections.

ENTRY OF AMENDMENTS

The proposed amendments to the claim should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search. Finally, if the Examiner determines the amendments do not place the application in condition for allowance, entry is respectfully requested upon filing a Notice of Appeal herein.

CONCLUSION

In light of the above amendments and remarks, the application should be in condition for allowance. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants’ attorney at the address or telephone number

given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Todd E. North".

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Encl: Petition for 1-month Extension of Time

Date: April 25, 2008

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